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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,130	07/11/2003	Donald R. Owen	040219.03	2946

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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,130	OWEN ET AL.	
	Examiner	Art Unit	
	WILLIAM H. BEISNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *228-235,244-271 and 274-281* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *228-235,244-271 and 274-281* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The finality of the rejection of the last Office is withdrawn in view of the new grounds of rejection set forth below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 228, 230-233, 235 and 274-278 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657).

The reference of McKelvey et al. discloses a system for holding an organ of during perfusion, storage and transport of the organ, comprising: a portable housing (31) for holding the organ; an organ perfusion apparatus (30) adapted to receive the portable housing and the portable housing is configured (1) to hold the organ independently from either of the organ perfusion apparatus, (2) to be separately received by the organ perfusion apparatus for perfusion of the organ, and (3) to allow perfusion, storage, and transport of the organ without removal of the organ from the portable housing.

With respect to claim 228, while the reference of McKelvey et al. discloses that the portable housing (31) can be inserted into a parent device (organ perfusion device, 30) without compromising sterility and that the portable housing (31) allows transfer of an organ contained therein from one transportation device to another wherein one device is a portable hand-carried device and the other is a larger non-portable device (organ perfusion device, 30) at the organ destination, the reference fails to specifically disclose that the portable hand-carried device is a perfusion device (See column 6, lines 1-19, reproduced below).

Since the unit 31 is removable, the bulk of the device can be put aside, while the much smaller and more easily handled unit 31 can be taken directly to a location more proximate where the organ is to be excised. The removable organ unit 31 allows an organ to be harvested in the sterile field of an operation room, housed within the sterile organ reservoir 10, and placed into the removable organ unit 31. Only the reservoir 10 and its lid 32 are carried into the sterile field. The unit 31 is, thereafter, inserted into the parent device and connected to the rest of the system without compromising sterility.

The removable unit 31 also allows the transfer of an organ contained therein from one transportation device to another (e.g., where the organ is transferred from a portable hand-carried device to a larger non-portable device at the organ destination). In alternative embodiments, the removable

The reference of Bacchi et al. discloses that it is conventional in the art to transport an organ within a portable housing (60) which is similar to the portable housing (31) of McKelvey et al. The reference of Bacchi et al. discloses that the portable housing is received within a portable hand-carried transportation device (10) that allows perfusion while the organ is transported in the hand-carried device (10).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to transport the organ unit (31) of McKelvey in a portable hand-carried device as taught by the reference of Bacchi et al. for the known and expected result of providing improved control of the transportation/preservation condition of the organ while transported in the hand-carried device (See column 1, line 34, to column 2, line 66). When providing a base perfusion unit and separate transportation unit which also is a perfusion device as suggested above, the portable housing would be capable of (1) holding the organ independently from either of the organ perfusion (base unit) or the transporter (transportation unit); (2) being received by the transporter for transport of the organ; (3) being separately received by the organ perfusion apparatus for

perfusion of the organ; and (4) allow perfusion, storage, and transport of the organ without removal of the organ from the portable housing. Note the transportation unit suggested and discussed above would be a portable organ perfusion apparatus.

With respect to claims 230 and 235, the portable housing (31) includes tubing and connection devices to allow connection to either a perfusion or transporter device (See Figures 4 and 5).

Claim 231 differs by reciting that the portable housing (31) includes a handle.

In the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of one having ordinary skill in the art to provide the housing of the primary reference with a handle so as to facilitate the removal of the housing from the perfusion devices and/or facilitate the transport of the portable housing itself.

With respect to claim 232, while the reference is silent with respect to the specific material of container (10), in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ a transparent material for the known and expected result of allowing observation of the contents of the container without removal of the lid which would compromise the sterility of the contents of the container.

With respect to claim 233, transfer of the portable housing (31) between a base unit and transportation unit as suggested and discussed above would meet the limitations required of claim 233.

With respect to claims 274 and 275, the perfusion apparatus disclosed by the reference of McKelvey et al. includes a diagnostic device (See column 10, line 55, to column 11, line 29).

With respect to the recited organ fitting and tube of claims 276-279, the reference of McKelvey et al. discloses an organ fitting (10) and tubing (39) wherein the organ fitting (10) is configured to hold the organ independently and be removable from any of the organ perfusion apparatus, the transporter or portable housing and to be received by the portable housing (31).

6. Claims 229 and 234 are rejected under 35 U.S.C. 103(a) as being unpatentable McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657) taken further in view of Fahy et al.(WO 96/29865).

The combination of the references of McKelvey et al. and Bacchi has been discussed above.

Claims 229 and 234 differ by reciting that the system includes a diagnostic device adapted to receive the housing.

The reference of Fahy et al.('865) discloses that it is conventional in the art to provide an organ perfusion system that is capable of evaluating the organ that is perfused within the device (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an additional system that is compatible with the organ housing for providing evaluation of the organ as suggested by the reference of Fahy et al.('865). Construction of the device such that the organ housing can be interfaced with the system without removal of the organ from the housing would have been obvious for the known and expected result of allowing the organ to be interfaced with a plurality of systems without being exposed to the environment and/or contaminated from unnecessary handling.

7. Claims 244, 246-253, 255, 256, 258-263, 265 and 276-279 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657) taken further in view of Fahy (US 5,586,438) and Armstrong et al.(US 6,238,908).

The combination of the references of McKelvey et al. and Bacchi has been discussed above.

With respect to claims 244 and 256, the reference of McKelvey et al. fails to disclose the use of transferable data with respect to the portable housing.

The reference of Fahy discloses the use of a microprocessor for data tracking (See column 16, lines 6-12), however, the reference does not disclose that the portable housing includes transferable data regarding the housing and its contents.

The reference of Armstrong et al. discloses that it is known in the art to provide a portable culture device with a memory device for interfacing the portable device with a plurality of different system devices (See column 10, line 58, to column 11, line 7, and column 15, lines 27-50).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with transferable data regarding the housing and its contents as is conventional in the art for transferring stored data between different system devices that interface with the portable housing.

With respect to claims 246 and 258, the portable housing includes tubing and connection devices (See Figures 4 and 5 of McKelvey).

Claim 247 differs by reciting that the portable housing (31) includes a handle.

In the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of one having ordinary skill in the art to provide the housing of the primary reference with a handle so as to facilitate the removal of the housing from the perfusion devices and/or facilitate the transport of the portable housing itself.

With respect to claims 248 and 259, the reference of Armstrong et al. discloses the use of a tag device (206).

With respect to claims 249-252 and 260-263, the specific information recorded and transferred would have been well within the purview of one having ordinary skill in the art based merely on the intended use of the organ.

With respect to claims 253 and 265, the system devices when used as recited above would be capable of receiving the data from the housing.

With respect to claim 255, the bottom portion of the housing is liquid-tight and configured to collect medical fluid.

With respect to the recited organ fitting and tube of claims 276-279, the reference of Fahy discloses an organ fitting (13) and tubing (110). As a result, it would have been well within the purview of one having ordinary skill in the art to provide the portable housing of the modified primary reference with an organ fitting and tubing as suggested by the reference of Fahy for the known and predictable result of providing a means recognized in the art for supporting an organ within an organ transport container.

8. Claims 245 and 257 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657), Fahy (US 5,586,438) and Armstrong et al.(US 6,238,908) taken further in view of Fahy et al.(WO 96/29865).

The combination of the references of McKelvey et al., Bacchi et al, Fahy and Armstrong et al. has been discussed above.

Claims 245 and 257 differ by reciting that the system includes a diagnostic device adapted to receive the housing.

The reference of Fahy et al.('865) discloses that it is conventional in the art to provide an organ perfusion system that is capable of evaluating the organ that is perfused within the device (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an additional system that is compatible with the organ housing for providing evaluation of the organ as suggested by the reference of Fahy et al.('865). Construction of the device such that the organ housing can be interfaced with the system without removal of the organ from the housing would have been obvious for the known and expected result of allowing the organ to be interfaced with a plurality of systems without being exposed to the environment and/or contaminated from unnecessary handling.

9. Claims 254 and 271 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657), Fahy (US 5,586,438) and Armstrong et al.(US 6,238,908) taken further in view of Coble et al.(US 5,451,524).

The combination of the references of McKelvey et al., Bacchi et al., Fahy and Armstrong et al. has been discussed above.

Claims 254 and 271 differ by reciting that the system includes an image recording device.

The reference of Coble et al. discloses that it is known in the art to study or observe cultured or perfused organ tissue sample over time with a video camera (See column 9, lines 44-52).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to monitor the contents of the housing over time with an imaging device for the known and expected result of optically monitoring the condition of the organ over time.

10. Claims 264, 266-270, 280 and 281 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657), Fahy (US 5,586,438) and Armstrong et al.(US 6,238,908) taken further in view of Schafer (US 6,300,875).

The combination of the references of McKelvey et al., Bacchi et al., Fahy and Armstrong et al. has been discussed above.

While the reference of Fahy discloses the transport of the housing by airplane from one point to another, the reference is silent with respect to computer tracking of the housing.

The reference of Schafer discloses that it is conventional in the art to track a portable package using a GPS system and networked computer system (See the abstract and Figure 1).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to track the organ housing using a system as disclosed by the reference of Schafer for the known and expected result of providing a means recognized in the art for tracking a portable package.

Response to Arguments

11. Applicant's arguments, see pages 2-5, filed 3/16/2009, with respect to the rejection(s) of the claims under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the combination of the references of McKelvey et al.(EP 0 376 763) in view of Bacchi et al.(US 5,285,657).

With respect to the reference of McKelvey et al., Applicants argue that the claims are not obvious in view of the reference of McKelvey et al. because the hand-carried and/or portable transportation device discussed by the reference of McKelvey et al. is not a perfusion device (See pages 2-5 of the response dated 3/16/2009).

In response, the reference of Bacchi et al.(US 5,285,657) has been cited as a teaching that it is known in the art to transport an organ within a hand-carried and/or portable perfusion device.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-

1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner
Art Unit 1797

/WHB/